



UNITED STATES PATENT AND TRADEMARK OFFICE

OCT 13 2009

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 5,677,331 was filed on June 5, 2009, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, Coartem™ (artemether/lumefantrine), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved.<sup>1</sup> Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

---

<sup>1</sup>The filing of the application on June 5, 2009, was timely, given the NDA approval date of April 7, 2009. Applicant, however, misidentified at section 5 on page 3 of the application the last day the application may be submitted as June 6, 2009, pursuant to 37 C.F.R. § 1.740(a)(5). Under both 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), a PTE applicant has sixty days to submit a PTE application, with the first day of that sixty-day period beginning on the FDA approval date. The absolute deadline for filing the present PTE Application is thus June 5, 2009, or sixty days from April 7, 2009, starting the count of the sixty-day period on April 7, 2009. The Federal Circuit in *Unimed, Inc. v. Quigg*, 12 USPQ2d 1644, 1646, made clear that "section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date."

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

A handwritten signature in cursive script, appearing to read "Mary C. Tull", written over a horizontal line.

Mary C. Tull

Legal Advisor

Office of Patent Legal Administration

Office of the Deputy Commissioner

for Patent Examination Policy

cc: Jennifer C. Chapman  
Novartis  
One Health Plaza, Bldg 101  
East Hanover, NJ 07936-1080